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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/188,051	11/06/1998	BRET A. SHIRLEY	5784-25	3829

7590

09/24/2002

Chiron Corporation
Intellectual Property Dept.
4560 Horton Street
Emeryville, CA 94608-2916

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/24/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Applicati n No.

09/188,051

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 29-48 and 85-112.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issue under 35 USC 112, second paragraph. In the amendment of September 9, 2002, claims 31, 35-39, 46 and 88-106 have been amended to use the term "at least about pH 5.5" or "of about...to about...". Applicants' response has been fully considered, however, claims 29-48 and 85-112 remain rejected under 35 USC 112, second paragraph.

If applicants' amendment were entered, it would have the following response:

1. Claims 29-48 and 85-112 are rejected under 35 USC 112, second paragraph as being indefinite because of the use of the term "at least about pH 5.5" or "at least about 12 mg". The term "at least about pH 5.5" or "at least about 12 mg" renders the claim indefinite; it is unclear what pH the composition has, it appears that the composition can have a pH greater than 5.5 as to "at least", and in the same time it can also have a pH less than 5.5 as to "about"; it is also unclear that at what concentration IGF-I or IGF-I analog is present in the composition, e.g., IGF-I or IGF-I analog can be greater than 12 mg as to "at least", and in the same time it can also be less than 12 mg as to "about". Claims 30-45, 47-48, 86-98, 100 and 102-112 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend. In response, applicants indicate the term "at least about" is definite, and the word "about" is often used in claims to define a numerical quantity and to avoid literal infringement by making minor modification. Applicants further assert that the term "exceeding about" is ruled as being definite by Federal Circuit. The argument is not found persuasive because each application is examined according to its own merits, and the term "at least about pH 5.5" indicates the pH can be greater than 5.5, in the same time it can be less than 5.5, which is indefinite.

2. Claim 35, for example, is indefinite because of the use of the term "of about.... to about...". The term "of about.... to about..." renders the claim indefinite, it is unclear whether the concentration of arginine is below 1 M as to "to 1M", or above 1M as to "about 1M". See also claims 36-39, 88-92, and 102-106. Use of the term "of aboutto..." is suggested. In response, applicants indicate the term "of about.... to about..." is definite. The argument is not found persuasive because the term "of about 10 mM to about 1 M", for example, indicates the concentration can be below 1 M, in the same time it can also be above 1M.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, second paragraph.

Continuation of 10. Other: The substituted declaration filed September 17 is acknowledged.

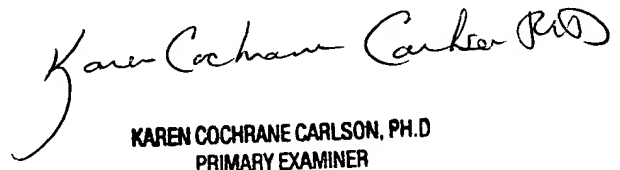
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
September 23, 2002

CMK


KAREN COCHRAN CARLSON, PH.D.
PRIMARY EXAMINER